

insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionnaire to the employer. In order to assure high response rates, Census will follow-up with a second mailing at an

acceptable interval, followed by a telephone call to collect data from those who have not responded by mail. For large organizational respondents with high burdens, such as State employers and very large firms, Census will, if

needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats and use of special forms.

#### Estimated Annual Respondent Burden

Annual number of respondents	Estimated hours per respondent	Estimated total annual burden hours	Estimated annual cost to the government
33,839 .....	.5	19,369	\$7,000,000

Estimates of annual respondent burden are based upon experience from collection of the previous three MEPS—IC surveys.

Copies of these proposed collection plans and instruments can be obtained from the AHRQ Reports Clearance Officer (see above).

Dated: December 15, 1999.

**John M. Eisenberg,**

Director.

[FR Doc. 99-32942 Filed 12-20-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99F-5322]

#### United States Department of Agriculture, Food Safety and Inspection Service; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the United States Department of Agriculture, Food Safety and Inspection Service has filed a petition proposing that the food additive regulations be amended to increase the maximum dose of ionizing radiation permitted in the treatment of poultry products, include specific language intended to clarify the poultry products covered by the regulations, and remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen.

**FOR FURTHER INFORMATION CONTACT:** Rudaina H. Alrefai, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 100 C St. SW., Washington, DC 20204, 202-418-3034.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive

petition (FAP 9M4696) has been filed by the United States Department of Agriculture, Food Safety and Inspection Service, 300 12th St. SW., rm. 112, Washington, DC 20250. The petition proposes to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) in item 6. of the table in paragraph (b) to: (1) Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products (2) include specific language intended to clarify the poultry products covered by the regulations and (3) remove the limitation that any packaging used during irradiation of poultry shall not exclude oxygen.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 3, 1999.

**Alan M. Rulis,**

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-5125]

#### Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing."

This guidance is neither final nor is it in effect at this time. This guidance provides labeling recommendations for over-the-counter sample collection systems for drugs of abuse testing and is being issued as a result of FDA's proposed reclassification of over-the-counter sample collection systems for drugs of abuse testing as class I restricted devices.

**DATES:** Submit written comments concerning this draft guidance by March 22, 2000.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments on this draft guidance to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Joseph Hackett, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3084.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of March 5, 1998 (63 FR 10792), FDA published a proposed rule that would reclassify over-the-counter (OTC) sample collection systems for drugs of abuse testing from class III (premarket approval) to class I (general controls),